



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0288]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#219) entitled “Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.”

This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to provide recommendations on how to use stability data generated in accordance with the principles detailed in the VICH guidance entitled “Stability Testing of New Veterinary Drug Substances and Medicinal Products, GL3(R)” to propose a retest period or shelf life in a registration application.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Mai Huynh,
Center for Veterinary Medicine, (HFV-142),
Food and Drug Administration,
7500 Standish Place,
Rockville, MD 20855,
240-276-8273,
Mai.huynh@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (#219) entitled, “Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51.” In recent years, many important initiatives have been undertaken by regulatory authorities and industry

associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, the European Medicines Evaluation Agency, the European Federation of Animal Health, the Committee on Veterinary Medicinal Products, FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the

preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Statistical Evaluation of Stability Data

The VICH Steering Committee held a meeting on November 14, 2011, and agreed that the draft guidance document entitled “Draft Guidance for Industry on Statistical Evaluation of Stability Data, VICH GL51” should be made available for public comment. This draft VICH guidance document is intended to provide recommendations on how to use stability data generated in accordance with the principles detailed in the VICH guidance entitled, “Stability Testing of New Veterinary Drug Substances and Medicinal Products, GL3(R)” to propose a retest period or shelf life in a registration application. This draft guidance describes when and how extrapolation can be considered when proposing a retest period for a drug substance or a shelf life for a veterinary medicinal product that extends beyond the period covered by available data from the stability study under the long-term storage condition.

This draft guidance addresses the evaluation of stability data that should be submitted in registration applications for new molecular entities and associated veterinary medicinal products. The draft guidance provides recommendations on establishing retest periods and shelf lives for drug substances and veterinary medicinal products intended for storage at or below “room temperature.” It covers stability studies using single- or multi-factor designs and full or reduced designs.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." In addition, guidance documents must not include mandatory language such as "shall," "must," "require," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this draft guidance have been approved under OMB control number 0910-0032.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: March 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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